K120334

JUN - 8 2012

510(K) SUMMARY

Viva EB

510(k) Number K_____

Applicant's Name: ETView Ltd.
17 Tchelet Street
Misgav Business Park
M.P Misgav 20174
Israel
Tel: (972)72-260-7063
Fax: (972)72-260-7263

Contact Person: Yoram Levy, Qsite
31 Haavoda St.
Binyamina, Israel 30500
Tel (972)4-638-8837
Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: ***Viva EB***

Device Type: Endobronchial Blocker

Preparation Date: January 31, 2012

Classification: **Regulatory Name:** Tracheal/bronchial differential ventilation tube
Product Code: CBI
Regulation No: 21 CFR 868.5740
Class: II
Classification Panel: Anesthesiology

Device Description:

The ETView ***Viva EB*** is designed to administer one-lung ventilation, by using a conventional endotracheal tube and a fiber optic bronchoscope. The device consists of a bronchial blocker tube, advanced through an endotracheal tube, and a joint connector, connecting the bronchial blocker tube to the endotracheal catheter. A cuff, incorporated at the distal tip of the tube, is inflated to block the targeted bronchus.

Intended Use Statement:

The ETView Viva EB is used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia.

Predicate Devices: Substantial equivalence to the following predicate devices is claimed:

Device Name	510k No	Date of Clearance
Daiken Medical Coopdech Endobronchial Blocker Tube	K071694	March 20, 2008
Cook Incorporated 7.0 Fr. Endobronchial Blocker	K021920	August 14, 2002

Performance Standards

Viva EB was tested and complies with the following standards:

- ISO 5361:1999 Anaesthetic and respiratory equipment -- Tracheal tubes and connectors
- ANSI/AAMI/ISO 11135-1:2007 Sterilization of health care products — Ethylene oxide
- ISO 14971-1:2007 Risk management for medical devices
- ISO 10993-1:2003(E), Biological evaluation of medical devices -- Part 1: Evaluation and testing

A detailed description appears in **Section 14.**

Performance Testing

Performance testing demonstrated that the ***Viva EB*** is as safe and effective as the cleared predicate devices.

The following performance tests were conducted:

- Analysis of cuff to shaft bond strength and burst test
- Analysis of deflection angle
- Analysis of cuff shape at various pressure
- Analysis of cuff dimension at various volumes
- Analysis of balloon cuff inflation retention
- The dimension and the ports of the joint connector
- Cuff Herniation
- Cuff Resting Diameter
- Cuff Symmetry
- Resistance to Tube Collapse
- VivaSight-SL (TVT^{TM}) Blocker Compatibility

Comparison to the Predicate Devices

The intended use of the Viva EB is identical to the intended use of Daiken Medical Coopdech Endobronchial Blocker Tube, cleared under K071694.

Both the ETView Viva EB and Daiken Medical Coopdech Endobronchial Blocker Tube are designed to administer one-lung ventilation, by using a conventional endotracheal tube and a fiber optic bronchoscope. The device parts, the structure, the principle of operation and the sterilization method of the Viva EB are similar to the cleared Coopdech Endobronchial Blocker Tube.

The minor differences between the Viva EB and its predicate devices do not raise any new questions of safety or efficacy. Moreover, performance testing demonstrated that the Viva EB is as safe and effective as the predicate devices. Thus, the Viva EB is substantially equivalent to Daiken Medical Coopdech Endobronchial Blocker Tube and Cook Incorporated 7.0 Fr. Endobronchial Blocker.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Etview Limited
C/O Mr. Yoram Levy
Regulatory Consultant
Qsite
31 Haavoda Street
Binyamina, Israel 30500

JUN - 8 2012

Re: K120334
Trade/Device Name: Viva EB
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: II
Product Code: CBI
Dated: May 23, 2012
Received: May 29, 2012

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: *Viva EB*

Indications for Use: The ETView Viva EB is used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia.

Prescription Use _X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
510(k) Number

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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